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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,906	03/17/2004	Gary K. Michelson	101.0058-03000	5309
22882 7590 12/10/2008 MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 12/10/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,906	<b>Applicant(s)</b> MICHELSON, GARY K.	
	<b>Examiner</b> Richard Shaffer	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-42 and 44-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-42 and 44-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The amendments to the claims filed on October 14<sup>th</sup>, 2008 are acknowledged and accepted by the examiner. The previous rejections under 35 U.S.C. 112, first paragraph are hereby withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10, 13-16, 18-29, 35, 38-42 and 44-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Caesar (US Patent 2,825,329).

Caesar discloses a device (**Figures 1-3**) comprising: a low profile plate (**150**) with a substantial (broad limitation, how much is "substantial") portion of the bone-contacting surface being flat along a direction parallel to its length as well as width; at least two bone screw receiving holes (**156**) receiving bone screws (**158**) arranged side-by-side; a locking element (**140**) capable of locking the screws (**158**) either through the use as shown in **Figures 1-3** or can also merely cover the top of plate (**150**) and be rotated, slid, etc into and out of alignment for allowing the screws through holes (**156**); locking element (**140**) having a circular head (**142**) with a cut-out (as seen in **Figure 2**).

In regard to the limitations stating the locking element is moveably attached to the implant prior to the insertion of the bone screws, the device is inherently capable of performing the claimed function.

Claims 7-29, 35 and 38-41 rejected under 35 U.S.C. 102(b) as being anticipated by Tornier (US Patent 4,488,543).

Tornier discloses a device (**Figures 1-3**) comprising: a low profile plate (**2**) with a bone contacting surface having a convex curvature along the length of the plate; **[First Interpretation]** three bone screw receiving holes (**6**) receiving bone screws (**3/3a**) arranged side-by-side; a locking element (**9** and **11** together); portion (**11**) of the locking element is elastic and thus can be pulled (partially rotated about an axis) out of the way of an inserting screw should one wish to do so; the locking element has a circular head (**11**) with a cutout (hole that allows **9** to pass through); **[Second Interpretation]** four bone screw receiving holes (**6** and **8**) receiving bone screws (**3/3a** and **9**); and a locking element (**11**) which can be rotated in order to allow insertion of at least two bone screws (**3/3a**).

In regard to the limitations stating the locking element is moveably attached to the implant prior to the insertion of the bone screws, the device is inherently capable of performing the claimed function.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caesar (US Patent 2,825,329).

Caesar discloses all of the claimed limitations except for the use of a second locking element and thereby a second pair of bone screw receiving holes and making the device with a fusion promoting substance such as bone or bone morphogenetic protein.

It is well known in the art to utilize to have additional components should certain parts be defective, if a patient requires additional stabilization (for example two fractures), etc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided for an additional locking element and plate in order to account for issues of defective parts or the need for additional fracture fixation.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use fusion promoting substances such as bone and bone morphogenetic protein, since it has been held to be within the skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

Claims 30-34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tornier (US Patent 4,488,543).

Tornier discloses all of the claimed limitations except for the use of a second locking element and thereby a second pair of bone screw receiving holes and making

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the device with a fusion promoting substance such as bone or bone morphogenetic protein.

It is well known in the art to utilize to have additional components should certain parts be defective, if a patient requires additional stabilization (for example two fractures), etc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided for an additional locking element and plate in order to account for issues of defective parts or the need for additional fracture fixation.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use fusion promoting substances such as bone and bone morphogenetic protein, since it has been held to be within the skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

### ***Double Patenting***

The following patents and patent applications have been considered for double patenting in the examination of this application:

#### **Patents:**

- 6,936,050   - 6,926,718   - 6,454,771   - 7,044,952   - 6,527,776   - 6,193,721  
- 6,936,051   - 6,398,783   - 7,041,105   - 7,077,844   - 7,118,573   - 6,383,186  
- 6,416,528   - 6,428,542   - 6,592,586   - 6,616,666   - 6,620,163   - 6,712,818  
- 6,916,320   - 6,969,390   - 7,074,221   - 7,097,645   - 7,112,202   - 7,115,130  
-6,139,550

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**Applications:**

- 10/926,734                      - 11/110,161                      - 11/128,556

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-42 and 44-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

claims 1-173 of U.S. Patent No. **6,193,721**

claims 1-39 of U.S. Patent No. **6,936,051**

claims 1-117 of U.S. Patent No. **6,398,783**

in view of Reisberg (US Patent 5,468,242).

**Comparison of Current Application against Conflicting Patents:**

**'721 Patent:** **Concave** (in dependent claims, e.g. 7, 10), **Silent** in independent claims (1, 28) instead of **convex/flat**; locking element for covering first and second bone screw receiving holes.

**'051 Patent:** **Concave** instead of **convex/flat**; lock for at least two bone screw receiving holes.

**'783 Patent:** **Concave** instead of **convex/flat**; lock for at least two bone screws (inserted in two bone screw receiving holes).

Reisberg teaches (**Column 1, Lines 5-20**) that having implants that conform to the bone surface/anatomical shape (e.g. convex, flat, and concave) is desired. One having ordinary skill in the art at the time the invention was made would have developed a device that either was pre-shaped or moldable to conform to the anatomy to provide for a low profile fit that would 1) minimize external visualization of implant and therefore embarrassment of patient 2) irritation from inflammation 3) allow fixation members (screws, tacks, pins, etc) to have greater holding force (instead of having a significant portion hanging out of the bone). Therefore, applicant's numerous patents attempting to differentiate bone plates on the premise of concave vs. convex/flat are not novel. The mere shaping of an interface surface to conform to the intended bone to which it is to be placed is already known to be desired and beneficial.

Any additional difference between the previous patents and the current application lies in the fact that the claims (taking into account dependent claims in several) in the patents include more elements and are thus more specific. The inventions therefore define a "species" of the "generic" invention of claim 7. It has been



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held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claims 7-42 and 44-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-72 of copending Application No. **10/926,734**

claims 1-62 of copending Application No. **11/128,556**

in view of Reisberg. As discussed in the patent section, applicant is merely reciting a concave base section with one application being "at least one" again with the other being "at least two" in regard to the bone receiving holes. Each one recites at least "two bone screws" in regard to a locking element

This is a provisional obviousness-type double patenting rejection.

### ***Response to Arguments***

Applicant's arguments filed on October 14<sup>th</sup>, 2008 have been fully considered but they are not persuasive.

In regard to applicant's remarks directed to the prior art reference of Caesar and Tornier, after additional consideration of the claimed limitations, it was felt that "moveably attached to said implant prior to the insertion of the bone screws" was a functional rather than structural limitation. The elements being interpreted as locking elements in both references are fully capable of being attached before any insertion of the bone screws. Applicant in the future may wish to tie together moveably attached with the initial and final position functional limitations. As it currently stands, the

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elements can be moveably attached at one point, then have "an initial position" which allows screws to enter the plate, and then "a final position" which blocks the screws.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733